

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner:	Not Yet Assigned	Art Unit:	
Re:	Application of:	Benjamin OSHLACK, et al.	
Serial No.:		Not Yet Assigned	
Filed:		November 3, 2003	
For:		TAMPER-RESISTANT ORAL OPIOID AGONIST FORMULATIONS	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

November 3, 2003

S i r:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Forms PTO-1449, which is a copy of the Forms submitted in connection with the parent application, US Serial No. 09/781,08, for consideration by the Examiner in connection with the examination of the above-identified patent application. Applicants are resubmitting these forms in order to provide for the printing of the references contained therein on the front of any patent that may issue.

Applicants also respectfully advise the Examiner of the following issued U.S. patents and co-pending U.S. patent applications which are commonly assigned to the owners of the instant application:

U.S. Patent Application Serial No. 10/244,783, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed September 16, 2002, which is a continuation application of

U.S. Patent Application Serial No. 09/815,167, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed March 22, 2001, now U.S. Patent No. 6,475,494, issued on November 5, 2002, which is a continuation application of U.S. Patent Application Serial No. 09/218,662, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed December 22, 1998, now U.S. Patent No. 6,277,384, issued on August 21, 2001.

U.S. Patent Application Serial No. 09/992,936, "OPIOID AGONIST/OPIOID ANTAGONIST/ACETAMINOPHEN COMBINATIONS", filed November 5, 2001, which is a continuation application of U.S. Patent Application Serial No. 09/503,020, "OPIOID AGONIST/OPIOID ANTAGONIST/ACETAMINOPHEN COMBINATIONS", filed February 11, 2002, now U.S. Patent No. 6,375,957, issued on April 23, 2002, which is a continuation-in-part of U.S. Patent Application Serial No. 09/218,662, "OPIOID AGONIST/ANTAGONIST COMBINATIONS", filed December 22, 1998, now U.S. Patent No. 6,277,384, issued on August 21, 2001.

U.S. Patent Application Serial No. 09/815,162, "METHOD OF PREVENTING ABUSE OF OPIOID DOSAGE FORMS", filed March 22, 2001, which is a continuation application of U.S. Patent Application Serial No. 09/218,663, "METHOD OF PREVENTING ABUSE OF OPIOID DOSAGE FORMS", filed December 22, 1998, now U.S. Patent No. 6,228,863, issued on May 8, 2001.

U.S. Patent Application Serial No. 09/781,076, "CONTROLLED-RELEASE COMPOSITIONS CONTAINING OPIOID AGONIST AND ANTAGONIST", filed February 8, 2001, pending.

U.S. Patent Application Serial No. 10/199,972, "PHARMACEUTICAL COMBINATIONS OF OXYCODONE AND NALOXONE", filed July 18, 2002, pending.

U.S. Patent Application Serial No. 10/213,919, "OPIOID AGONIST FORMULATIONS WITH RELEASABLE AND SEQUESTERED ANTAGONIST", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,408, "SEQUESTERED ANTAGONIST FORMULATIONS", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/213,921, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST AND BITTERING AGENT", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,409, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST, AND IRRITANT", filed August 6, 2002, pending.

U.S. Patent Application Serial No. 10/214,413, "PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST AND GELLING AGENT", filed August 6, 2002, pending.

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii) the Examiner's attention is directed to Exhibit A attached herewith which contains the following:

(i) specifications and claims for pending application serial nos. 09/781,076; 10/199,972; 10/213,919; 10/214,408; and 10/213,921;

(ii) claims of pending application serial no. 10/244,783, which has the same specification as U.S. Patent No. 6,277,384, listed as reference AB on the Form PTO 1449 submitted with the Information Disclosure Statement of November 7, 2001;

(iii) claims of pending application serial no. 09/992,936, which has the same specification as U.S. Patent No. 6,375,957, listed as reference LD on enclosed Form PTO-1449;

(iv) claims of pending application serial no. 09/815,162, which has the same specification as U.S. Patent No. 6,228,863, listed as reference AA on the Form PTO 1449 submitted with the Information Disclosure Statement of November 7, 2001;

(v) claims of pending application serial nos. 10/214,413; and 10/214,409, which have the same specification as that of application serial no. 10/213,921, mentioned above in paragraph (i).

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. However, if it is determined that any additional fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Robert J. Paradiso
Reg. No. 41,240

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Oshlack, et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	3	9	6	5	2	5	6	06/22/1976	Leslie	424	22		
	AB	4	2	3	7	1	4	0	12/02/1980	Dudzinski	424	260		
	AC	4	3	6	6	3	1	0	12/28/1982	Leslie	536	56		
	AD	4	4	4	3	4	2	8	04/17/1984	Oshlack, et al.	424	22		
	AE	4	8	2	8	8	3	6	05/09/1989	Elger, et al.	424	419		
	AF	4	8	3	4	9	6	5	05/30/1989	Martani, et al.	424	488		
	AG	4	8	3	4	9	8	4	05/30/1989	Goldie, et al.	424	488		
	AH	4	8	3	4	9	8	5	05/30/1989	Elger, et al.	424	488		
	AI	4	8	4	4	9	0	7	07/04/1989	Elger, et al.	424	465		
	AJ	4	8	4	4	9	0	9	07/04/1989	Goldie, et al.	424	480		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
		YES	NO											
	AK	0	1	9	3	3	5	5	09/03/1986	Europe (A3)	A61K	31/615		
	AL	0	3	1	9	2	4	3	06/07/1989	Europe (A1)	A61K	31/485		
	AM	0	3	1	9	2	4	3	11/07/1990	Europe (A2)	A61K	31/485		
	AN	0	0	0	1	3	7	7	01/13/2000	WO	A61K	31/00		
	AO	9	0	0	4	9	6	5	05/17/1990	WO	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AP	Translation of previously submitted German patent application DE 43 25 465												
	AQ	Alvarez-Fuentes, et al., "Effectiveness of Repeated Administration of a New Oral Naltrexone Controlled-Release System on Morphine Analgesia"; J. Pharm Pharmacol (2001), 53; pg. 1201-1205												
	AR	Alvarez-Fuentes, et al., "Preclinical Study of an Oral Controlled Release Naltrexone Complex in Mice"; J. Pharm Pharmacol (2000), 52; pg. 659-663												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081							
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.									
				FILING DATE: February 8, 2001		GROUP: 1615							
U.S. PATENT DOCUMENTS													
*EXAMINER INITIAL		DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
	BA	4	8	4	4	9	1	0	07/04/1989	Leslie, et al.	424	494	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
										YES	NO		
	BB												
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	BC	Archer, Sydney; "Historical Perspective on the Chemistry and Development of Naltrexone"; Naltrexone: Research Monograph 28 (1980) pg. 3-9											
	BD	Baum, et al., "The Impact of the Addition of Naloxone on the Use and Abuse of Pentazocine"; Public Health Reports (1987) Vol. 102, No. 4 pg. 426-429											
	BE	Rapaka, et al., "Discovery of Novel Opioid Medications"; NIDA Research Monograph 147 (1995) pg. 53-83											
	BF	Bloom, et al., "Clinical Studies with Naloxone/Methadone in a Ratio of 1:20"; 5 th National Conference on Methadone Treatment (1973) Vol 2, pg. 1342 - 1349											
	BG	Blachly, M.D., "Naloxone in Opiate Addiction"; Current Psychiatric Therapies (1976) pg. 209-213											
	BH	Briscoe, et al., "Methoclocinnamox: Time Course of Changes in Alfentanil-Reinforced Responding in Rhesus Monkeys"; Psychopharmacology (2000) 148: pg. 393-399											
	BI	Abstract of Bromm, et al., "A Sensitive Method to Evaluate Effects of Analgesics in Man"; Meth and Find Exptl Clin Pharmacol 5 (8) (1983) pg. 545-551											
	BJ	Bullingham, et al., "Clinical Pharmacokinetics of Narcotic Agonist-Antagonist Drugs"; Clinical Pharm. (1983) 8: 332-343											
	BK	Calimlim, et al., "Effect of Naloxone on the Analgesic Activity of Methadone in a 1:10 Oral Combination"; Clin Pharmacol and Thera (1974) Vol. 15; No. 6 pg. 556-564											
	BL	Caruso, et al., "Methadone and Naloxone in Combination (Naldone®) for the Treatment of Heroin Addicts"; Bristol Laboratories, pg. 1336-1341F											
	BM	Cherny, Nathan I., "Opioid Analgesics"; Drugs (1996) May; 51 (5) pg. 713-737											
	BN	Chiang, et al., "Clinical Evaluation of a Naltrexone Sustained-Release Preparation"; Drug and Alcohol Dependence (1985) 16, pg. 1-8											
	BO	Chiang, et al., "Kinetics of a Naltrexone Sustained-Release Preparation"; Clin. Pharmacol Thera (1984) Vol. 36, No. 5, pg. 704-708											
	BP	Comer, et al., "Depot Naltrexone: Long-lasting Antagonism of the effects of heroin in humans"; Psychopharmacology (2002) 159; pg. 351-360											
	BQ	Crabtree, et al., "Review of Naltrexone, a long-acting opiate antagonist"; Clinical Pharmacy, Vol 3 (1984) pg. 273-280											
EXAMINER							DATE CONSIDERED						
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	CA	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		4 8 6 7 9 8 5	09/19/1989	Heafield, et al.	424	461	
FOREIGN PATENT DOCUMENTS							
	CB	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	CC	Crain et al., "Antagonists of excitatory opioid receptor functions enhance morphine's analgesic potency and attenuate opioid tolerance/dependence liability"; Dept. Of Neuroscience, Albert Einstein College of Medicine, Pain 82 (1999) pg. 1-11					
	CD	Crain et al., "Antagonists of excitatory opioid receptor functions enhance morphine's analgesic potency and attenuate opioid tolerance/dependence liability"; Dept. Of Neuroscience, Albert Einstein College of Medicine, Pain 84 (2000) pg. 121-131					
	CE	Fink, et al., "Naloxone in Heroin Dependence"; Clin Pharm and Therapeutics, Vol 9, No. 5; pg. 568-577					
	CF	Fishman, et al., "Disposition of Naloxone-7,8- ³ H in Normal & Narcotic-Dependent Men"; J. of Pharm. and Experimental Therapeutics (1973) Vol 187, No. 3, pg. 575-580					
	CG	Fraser, Albert D., et al., "Clinical Toxicology of Drugs Used in the Treatment of Opiate Dependency"; Clinical Toxicology 1, (1990) Vol 10, No. 2, pg. 375-386					
	CH	Freye, et al., "Effects of Tramadol and Tilidine/Naloxone on Oral-Caecal Transit & Pupillary Light Reflex"; Arzneim.-Forsch/Drug Res. 50 (I) (2000) pg. 24-30					
	CI	Fudala, et al., "Effects of Burpenorphine and Naloxone in Morphine-Stabilized Opioid Addicts"; Drug and Alcohol Dependence 50 (1998) pg. 1-8					
	CJ	Fudala, et al., "Human Pharmacology and Abuse Potential of Nalmefene"; Clin Pharm and Thera (1991) Vol 49, 3, pg. 300-306					
	CK	Gal, et al., "Prolonged Blockade of Opioid Effect with Oral Nalmefene"; Clin Pharmacol Ther. (1986) pg. 537-542					
	CL	Gerra, et al., "Clonidine and Opiate Receptor Antagonists in the Treatment of Heroin Addiction"; J. Substance Abuse Treatment (1995) Vol 12, 1, pg. 35-41					
	CM	Ghodse, et al., "Opioid analgesics and narcotic antagonists"; Side Effects of Drugs (2000) Annual 23, Ch. 8, pg. 96-113					
	CN	Glatt, William, M.D. FACP, "A New Method for Detoxifying Opioid-Dependent Patients"; J. Substance Abuse Treatment (1999) Vol 17, No 3, pg. 193-197					
	CO	Gold, et al., "Rapid Opioid Detoxification during General Anesthesia"; Anesthesiology (1999) Vol 91, No 6, 1639-1647					
	CP	Greenwald, et al., "Comparative Clinical Pharmacology of Short-Acting <i>Mu</i> Opioids in Drug Abusers"; J. Pharm. and Experimental Therapeutics (1996) Vol 277, No 3, pg. 1228-1236					
EXAMINER				DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081							
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.									
				FILING DATE: February 8, 2001		GROUP: 1615							
U.S. PATENT DOCUMENTS													
*EXAMINER INITIAL		DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
	DA	4	9	4	0	5	8	7	07/10/1990	Jenkins, et al.	424	480	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER				DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION			
	DB										YES	NO	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	DC	Gupta, et al., "Morphine Combined with Doxapram or Naloxone"; Anaesthesia (1974) Vol 29 pg. 33-39											
	DD	Richter, et al., "Clinical Investigation on the Development of Dependence during Oral Therapy with Tramadol"; Arzneim-Forsch/Drug Res. 35 (No II) (1985) pg. 1742-1744											
	DE	Rosen, et al., "Effect of Clonidine Pretreatment on Naloxone-Precipitated Opiate Withdrawal"; J. of Pharm. and Experimental Ther. (1996) Vol 276, No 3, pg. 1128-1135											
	DF	Rosen, et al., "The effect of lamotrigine on naloxone-precipitated opiate withdrawal"; Drug and Alcohol Dependence (1998) Vol 52, pg. 173-176											
	DG	Rosen, et al., "A pilot study of dextromethorphan in naloxone-precipitated opiate withdrawal"; European J. of Pharm. (1996) Vol 307, pg. 251-257											
	DH	Schuh, et al., "Buprenorphine, Morphine and Naloxone Effects during Ascending Morphine Maintenance in Humans"; J. of Pharm. and Experimental Ther. (1996) Vol 278, 2, pg. 836-846											
	DI	Schuh, et al., "Onset, magnitude and duration of opioid blockade produced by buprenorphine and naltrexone in humans"; Psychopharmacology (1999) Vol 145, pg. 162-174											
	DJ	Stevens, et al., "Nonspecific Excitatory Effects of Morphine: Reverse-Order Precipitated Withdrawal and Dose-Dose Interactions"; Psychopharmacology (1981) Vol 75, pg. 210-211											
	DK	Stine, et al., "Reduction of Opiate Withdrawal-like Symptoms by Cocaine Abuse during Methadone and Buprenorphine Maintenance"; Am. J. Drug Alcohol Abuse (1994) Vol 20, (4), pg. 445-458											
	DL	Stine, et al., "Use of Drug Combinations in Treatment of Opioid Withdrawal"; J. of Clinical Psych. (1992) Vol 12, No. 3, pg. 203-209											
	DM	Stoller, et al., "Effects of buprenorphine/naloxone in opioid-dependent humans"; Psychopharmacology (2001) Vol 154, pg. 230-242											
	DN	Strain, et al., "Acute effects of buprenorphine, hydromorphone and naloxone in methadone-maintained volunteers"; J. of Pharm. and Experimental Ther. (1992) Vol 261, No. 3, pg. 985-993											
	DO	Strain, et al., "Effects of buprenorphine versus buprenorphine/naloxone tablets in non-dependent opioid abusers"; Psychopharmacology (2000) Vol 148, pg. 374-383											
	DP	Strain, et al., "Precipitated Withdrawal by Pentazocine in Methadone-Maintained Volunteers"; J. of Pharm. and Experimental Ther. (1993) Vol 267, No 2, pg. 624-634											
	DQ	Tai, et al., "Naltrexone: An Antagonist Therapy for Heroin Addiction"; NIDA (1997) 5 pages											
	DR	Umbricht, et al., "Naltrexone shortened opioid detoxification with buprenorphine"; Drug and Alcohol Dependence (1999) Vol 56, pg. 181-190											
EXAMINER							DATE CONSIDERED						
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.								
				FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS												
*EXAMINER INITIAL		DOCUMENT NUMBER					DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	EA	4	9	7	0	0	7	5	11/13/1990	Oshlack	424	451
FOREIGN PATENT DOCUMENTS												
		DOCUMENT NUMBER					DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
											YES	NO
	EB											
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)												
	EC	Vaccarino, et al., "Endogenous Opiates: 1999"; Peptides 21 (2000) pg. 1975-2034										
	ED	Wang, et al., "Inverse agonists and neutral antagonists at μ opioid receptor (MOR): possible role of basal receptor signaling in narcotic dependence"; J. of Neurochemistry (2001) Vol 77, pg. 1590-1600										
	EE	Way, et al., "Responsivity to Naloxone during Morphine Dependence"; Annals New York Academy of Sciences, pg. 252-261										
	EF	Weinberg, et al., "Sublingual absorption of selected opioid analgesics"; Clin Pharm Ther (1988) Vol 44, No 3, pg. 335-342										
	EG	Wells, et al., "In Vivo Pharmacological Characterization of SoRJ 9409, a Nonpeptidic Opioid μ -Agonists/ δ -Antagonist that Produces Limited Antinociceptive Tolerance and Attenuates Morphine Physical Dependence"; J. Pharm and Exper. Thera. (2001) Vol 297, No 2, pg. 597-605										
	EH	Wodak, Alex, "Drug Treatment for Opioid Dependence"; Australian Prescriber (2001) Vol 24, No 1, pg. 4-6										
	EI	Wright, et al., "Acute physical dependence in humans; repeated naloxone-precipitated withdrawal after a single-dose of methadone"; Drug and Alcohol Dependence (1991) Vol 27, pg. 139-148										
	EJ	Zhu, et al., "Naltrexone-precipitated morphine withdrawal in infant rat is attenuated by acute administration of NOS inhibitors but not NMDA receptor antagonists"; Psychopharmacology (2000) Vol 150, pg. 325-336										
	EK	Han, et al., "Mucoadhesive buccal disks for novel nalbuphine prodrug controlled delivery: effect of formulation variables on drug release and mucoadhesive performance"; International J. of Pharm (1999) Vol 177, pg. 201-209										
	EL	Handal, et al., "Naloxone"; Annals of Emergency Medicine (1983) Vol 12:7, pg. 438-445										
	EM	Harris, et al., "Buprenorphine and naloxone co-administration in opiate-dependent patients stabilized on sublingual buprenorphine"; Drug and Alcohol Dependence (2000) Vol 61, pg. 85-94										
	EN	Hawkes, et al., "Effect of an enteric-release formulation of naloxone on intestinal transit in volunteers taking codeine"; Aliment Pharm Ther (2001) Vol 15, pg. 625-630										
	EO	Högger, et al., "Comparison of tilidine/naloxone, tramadol and bromfenac in experimental pain: a double-blind randomized crossover study in healthy human volunteers"; International J. Clin Pharm and Ther (1999) Vol 37, No 8, pg. 377-385										
EXAMINER									DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.												

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081							
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Oshlack, et al.									
				FILING DATE: February 8, 2001		GROUP: 1615							
U.S. PATENT DOCUMENTS													
*EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	FA	4	9	8	7	1	3	6	01/22/1991	Kreek, et al.	514	282	
	FB	4	9	9	0	3	4	1	02/05/1991	Goldie, et al.	424	484	
	FC	5	0	7	1	6	4	6	12/10/1991	Malkowska, et al.	424	497	
	FD	5	0	9	1	1	8	9	02/25/1992	Heafield, et al.	424	457	
	FE	5	2	1	5	7	5	8	06/01/1993	Krishnamurthy	424	488	
	FF	5	2	2	6	3	3	1	07/13/1993	Thompson, et al.	73	865.9	
	FG	5	2	6	6	3	3	1	11/30/1993	Oshlack, et al.	424	468	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
												YES	NO
	FH												
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	FI	Budd, Keith, "Clinical use of Opioid Antagonists"; Bailliere's Clinical Anesthesiology (1987) Vol 1, No 4, pg. 993-1011											
	FJ	Crain, et al., "Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic cotreatment"; Proc. Natl. Acad. Sci (1995) Vol 92, pg. 10540-10544											
	FK	Howes, et al., "The Pharmacology of TR5109, a New Narcotic Agonist/Antagonist Analgesic"; NIDA Research (1979) pg. 99-105											
	FL	Leeling, et al., "Disposition and metabolism of codorphone in the rat, dog and man"; Drug Metabolism and Disposition (1982) Vol 10, No 6, pg. 649-653											
	FM	Amass, et al., "Efficacy of daily and alternate-day dosing regimens with the combination buprenorphine-naloxone tablet"; Drug and Alcohol Dependence (2000) Vol 58, pg. 143-152											
	FN	Hussain, et al., "Buccal and oral bioavailability of naloxone and naltrexone in rats"; (1987) Vol 36, pg. 127-130											
	FO	Jasinski, et al., "The human pharmacology and abuse potential of N-allylnoroxymorphone naloxone"; J. of Pharm and Exper Thera (1967) Vol 157, No. 2, pg. 420-426											
	FP	Jones, et al., "Nalmefene: blockade of intravenous morphine challenge effects in opioid abusing humans"; Drug and Alcohol Dependence (2000) Vol 60, pg. 29-37											
	FQ	Kanof, et al., "Clinical Characteristics of Naloxone-Precipitated Withdrawal in Human Opioid-Dependent Subjects"; J. of Pharm and Exper Thera (1992) Vol 260, No. 1, pg. 355-363											
	FR	King, et al., "Naltrexone Biotransformation and Incidence of Subjective Side Effects: A Preliminary Study"; Alcoholism: Clin and Exp Res (1997) Vol 21, No. 5, pg. 906-909											
EXAMINER									DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1133SERIAL NO.:
09/781,081

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S):
Oshlack, et al.FILING DATE:
February 8, 2001GROUP:
1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	GA	5	2	8	6	4	9	3	02/15/1994	Oshlack, et al.	424	468	
	GB	5	3	2	4	3	5	1	06/28/1994	Oshlack, et al.	106	153	
	GC	5	3	3	6	6	9	1	08/09/1994	Raffa, et al.	514	629	
	GD	5	3	5	6	4	6	7	10/18/1994	Oshlack, et al.	106	153	
	GE	5	4	1	1	7	4	5	05/02/1995	Oshlack, et al.	424	456	
	GF	5	4	6	0	8	2	6	10/24/1995	Merrill, et al.	424	470	
	GG	5	4	7	2	7	1	2	12/05/1995	Oshlack, et al.	424	480	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	GH	8	7	0	1	2	8	2	03/12/1987	WO	A61K	31/485		
	GI	0	1	3	2	1	8	0	05/10/2001	WO (A2)	A61K	31/485		
	GJ	0	1	6	8	0	8	0	09/20/2001	WO (A2)	A61K	31/00		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	GK	Kogan, et al., "Estimation of the Systemic Availability and other Pharmacokinetic Parameters of Naltrexone in Man after Acute and Chronic Oral Administration"; Res. Comm. in Chem. Path. and Pharm (1977) Vol 18, No. 1; pg. 29-34											
	GL	Kosten, Thomas R., M.D., "Buprenorphine for Benzodiazepine-Abusing Heroin Addicts"; Amer J. of Psychiatry (1994) Vol 1, pg. 151											
	GM	Kosten, et al., "Opioid antagonist challenges in buprenorphine maintained patients"; Drug and Alcohol Dependence (1990) Vol 25, pg. 73-78											
	GN	Kurland, et al., "Naloxone and the Narcotic Abuser: A Controlled Study of Partial Blockade"; Inter. J. of the Addictions (1974) Vol 9, No. 5, pg. 663-672											
	GO	Lee, et al., "Nalbuphine Coadministered with Morphine Prevents Tolerance and Dependence"; Anesth Analg (1997) Vol 84, pg. 810-815											
	GP	Lehmann, et al., "Influence of Naloxone on the Postoperative Analgesic and Respiratory Effects of Buprenorphine"; Eur J. Clin. Pharm. (1988) Vol 34, 343-352											
	GQ	Levine, et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J Clin Invest. (1988) Vol 82, pg. 1574 - 1577											

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Oshlack, et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	HA	5	4	7	8	5	7	7	12/26/1995	Sackler, et al.	424	489		
	HB	5	5	0	0	2	2	7	03/19/1996	Oshlack, et al.	424	476		
	HC	5	5	0	8	0	4	2	04/16/1996	Oshlack, et al.	424	468		
	HD	5	5	0	8	0	4	3	04/16/1996	Krishnamurthy	424	484		
	HE	5	5	4	9	9	1	2	08/27/1996	Oshlack, et al.	424	468		
	HF	5	5	5	2	4	2	2	09/03/1996	Gauthier, et al.	514	368		
	HG	5	5	9	1	4	5	2	01/07/1997	Miller, et al.	424	468		
	HH	5	6	0	1	8	4	5	02/11/1997	Buxton, et al.	424	495		
	HI	5	6	2	2	7	2	2	04/22/1997	Knott, et al.	424	494		
	HJ	5	6	3	9	4	7	6	06/17/1997	Oshlack, et al.	424	468		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	HK													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	HL	Loimer, et al., "Combined Naloxone/Methadone Preparations for Opiate Substitution Therapy"; J. of Substance Abuse Treatment (1991) Vol 8, pg. 157-160												
	HM	Martin, et al., "Bioavailability Investigation of a New Tilidine/Naloxone Liquid Formulation Compared to a Reference Formulation"; Arzneim.-Forsch./Drug Res. (1999) Vol 49, pg. 599-607												
	HN	Martin, et al., "Demonstration of Tolerance to and Physical Dependence on N-allylnormorphine (Nalorphine)"; J. of Pharm and Exper Thera (1965) Vol 150, No. 3, pg. 437-442												
	HO	Mendelson, et al., "Buprenorphine and naloxone combinations: the effects of three dose ratios in morphine-stabilized, opiate-dependent volunteers"; Psychopharmacology (1999) Vol 141, pg. 37-46												
	HP	Mendelson, et al., "Buprenorphine and Naloxone Interactions in Methadone Maintenance Patients"; Society of Biological Psychiatry (1997) Vol 41, pg. 1095-1101												
	HQ	Nutt, et al., "Methadone-naloxone mixtures for use in methadone maintenance programs"; Clin Pharma and Thera, Vol 15, No. 2, pg. 156-166												
	HR	Parwatikar, et al., "Methadone-naloxone in combination for the treatment of heroin addicts"; Clin Pharm and Thera, Vol 14, No. 6, pg. 941-948												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Oshlack, et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	IA	5	6	5	6	2	9	5	08/12/1997	Oshlack, et al.	424	468		
	IB	5	6	7	0	1	7	2	09/23/1997	Buxton, et al.	424	495		
	IC	5	6	7	2	3	6	0	09/30/1997	Sackler, et al.	424	490		
	ID	5	6	8	1	5	8	5	10/28/1997	Oshlack, et al.	424	494		
	IE	5	7	6	3	4	5	2	06/09/1998	Miller, et al.	514	282		
	IF	5	7	8	0	4	7	9	07/14/1998	Kim	514	282		
	IG	5	8	1	1	1	2	6	09/22/1998	Krishnamurthy	424	498		
	IH	5	8	3	4	4	7	7	11/10/1998	Mioduszewski	514	282		
	II	5	8	4	3	4	8	0	12/01/1998	Miller, et al.	424	484		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	IJ													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	IK	Pärwartikar, et al., "Naloxone-Methadone Combination for the Treatment of Opiate Dependence"; Missouri Institute of Psychiatry, pg. 1350-1354												
	IL	Pitts, et al., "Antinociceptive and Response Rate-Altering Effects of <i>Kappa</i> Opioid Agonists, Spiradoline, Enadoline and U69,593, Alone and in combination with Opioid Antagonists in Squirrel Monkeys"; J. Pharm and Exper Thera (1994) Vol 271, No. 3, pg. 1501-1508												
	IM	Preston, et al., "Buprenorphine and Naloxone alone and in combination in opioid-dependent humans"; Psychopharmacology (1988) Vol 94, pg. 484-490												
	IN	Preston, et al., "Differential Naltrexone Antagonism of Hydromorphone and Pentazocine Effects in Human Volunteers"; J. Pharm and Exper Thera (1993) Vol 264, No. 2, pg. 813-823												
	IO	Preston, et al., "Effects of Sublingually given naloxone in opioid-dependent human volunteers"; Drug and Alcohol Dependence (1990) Vol 25, pg. 27-34												
	IP	Bigelow, et al., "Abuse Liability Assessment of Buprenorphine-Naloxone Combinations"; Dept. of Psychiatry and Behavioral Sciences - The Johns Hopkins University School of Medicine, pg. 145-149												
	IQ	Wikler, et al., 'N-Allylnormorphine: Effects of single doses and precipitation of acute "Abstinence Syndromes" during addiction to morphine, methadone or heroin in man (post-addicts)'; N-Allylnormorphine During Narcotic Addiction (1953) pg. 8-20												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Oshlack, et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	JA	5	8	4	9	2	4	0	12/15/1998	Miller, et al.	264	460		
	JB	5	8	6	9	0	9	7	02/09/1999	Wong, et al.	424	473		
	JC	5	8	7	9	7	0	5	03/09/1999	Heafield, et al.	424	464		
	JD	5	8	9	1	4	7	1	04/06/1999	Miller, et al.	424	468		
	JE	5	9	0	8	8	4	8	06/01/1999	Miller, et al.	514	282		
	JF	5	9	5	8	4	5	2	09/28/1999	Oshlack, et al.	424	457		
	JG	5	9	5	8	4	5	9	09/28/1999	Chasin, et al.	424	490		
	JH	5	9	6	5	1	6	1	10/12/1999	Oshlack, et al.	424	457		
	JI	5	9	6	5	1	6	3	10/12/1999	Miller, et al.	424	468		
	JJ	5	9	6	8	5	5	1	10/19/1999	Oshlack, et al.	424	456		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	JK													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	JL	Zaks, et al., "Naloxone Treatment of Opiate Dependence"; JAMA (1971) Vol 215, No. 13, pg. 2108-2110												
	JM	Barton, et al., "Intranasal Administration of Naloxone by Paramedics"; Prehospital Emergency Care (2002) Vol 6, No. 1, pg. 54-58												
	JN	Blachly, Paul, H., M.D., "Naloxone in Opiate Addiction"; Current Psychiatric Therapies (1976) pg. 209-213												
	JO	Bashaw, et al., "Relative bioavailability of controlled-release oral morphine sulfate during naltrexone blockade"; Inter J. of Clin Pharm and Thera (1995) Vol 33, No. 9, 524-529												
	JP	Jasinski, D.R., "Assessment of the Abuse Potentiality of Morphinelike Drugs (Methods Used in Man)"; Drug Addiction (1977) pg. 197-258												
	JQ	Johnson, et al., "Buprenorphine and Naloxone for Heroin Dependence"; Substance Use Disorders (2000) pg. 519-526												
	JR	Strain, et al., "Opioid antagonist effects of dezocine in opioid-dependent humans"; Clin Pharm and Thera (1996) Vol 60, No. 2, pg. 206-217												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1133SERIAL NO.:
09/781,081

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S):
Oshlack, et al.FILING DATE:
February 8, 2001GROUP:
1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	KA	6	0	2	4	9	8	2	02/15/2000	Oshlack, et al.	424	476	
	KB	6	0	6	8	8	5	5	05/30/2000	Leslie, et al.	424	468	
	KC	6	0	7	7	5	3	2	06/20/2000	Malkowska, et al.	424	457	
	KD	6	0	7	7	5	3	3	06/20/2000	Oshlack, et al.	424	461	
	KE	6	1	0	3	2	5	8	08/15/2000	Simon	424	449	
	KF	6	1	0	3	2	6	1	08/15/2001	Chasin, et al.	424	459	
	KG	6	1	4	3	3	2	2	11/07/2000	Sackler, et al.	424	459	
	KH	6	1	4	3	3	2	8	11/07/2000	Heafield, et al.	424	489	
	KI	6	1	6	2	4	6	7	12/19/2000	Miller, et al.	424	468	
	KJ	6	2	1	0	7	1	4	04/03/2001	Oshlack, et al.	424	476	
	KK	6	2	5	4	8	8	7	07/03/2001	Miller, et al.	424	468	
	KL	6	2	6	1	5	9	9	07/17/2001	Oshlack, et al.	424	457	
	KM	6	2	9	4	1	9	5	09/25/2001	Oshlack, et al.	424	457	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	KN	0	1	3	7	7	8	5	05/31/2001	WO (A2)	A61K			
	KO	0	1	5	2	8	5	1	07/26/2001	WO (A1)	A61K	31/485		
	KP	0	1	8	5	2	5	7	11/15/2001	WO (A2)	A61P			
	KQ	0	1	9	3	8	5	2	12/13/2001	WO (A2)	A61K	31/00		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

KR	Preston, et al., "Abuse liability studies of opioid agonist-antagonists in humans"; Drug and Alcohol Dependence (1991) Vol 28, pg. 49-82
KS	Brennscheidt, et al., "Pharmacokinetics of Nortilidine and Naloxone after Administration of Tilidine/Naloxone Solution or Tilidine/Naloxone Sustained Release Tablets"; Arzneim.-Forsch./Drug Res. (2000) Vol 50, pg. 1015-1022

EXAMINER:

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Oshlack, et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	LA	6	3	0	6	4	3	8	10/23/2001	Oshlack, et al.	424	468		
	LB	6	3	2	6	0	2	7	12/04/2001	Miller, et al.	424	468		
	LC	6	3	3	5	0	3	3	01/01/2002	Oshlack, et al.	424	457		
	LD	6	3	7	5	9	5	7	04/23/2002	Kaiko, et al.	424	400		
	LE	6	3	8	7	4	0	4	05/14/2002	Oshlack, et al.	424	480		
	LF	6	3	9	9	0	9	6	06/04/2002	Miller, et al.	424	464		
	LG	6	4	7	5	4	9	4	11/05/2002	Kaiko, et al.	424	400		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	LH													
	LI													
	LJ													
	LK													
	LL													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	LM													
	LN													
	LO													
	LP													
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1133SERIAL NO.:
09/781,081

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S):
Curtis Wright et al.FILING DATE:
February 8, 2001GROUP:
1615

U.S. PATENT DOCUMENTS

*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5	9	9	8	4	3	4	12/99	Mitch et al.	514	210.16	
	AB	5	9	7	2	9	5	4	10/99	Foss	514	282	
	AC	5	9	6	8	5	4	7	10/99	Reder et al.	424	449	
	AD	5	9	4	2	2	4	1	8/99	Chasin et al.	424	426	
	AE	5	8	8	0	1	3	2	3/99	Hill	514	282	
	AF	5	8	6	6	1	6	4	2/99	Kuczynski et al.	424	472	
	AG	5	8	6	0	9	5	0	1/99	Demopoulos et al.	604	49	
	AH	5	8	5	8	0	1	7	1/99	Demopoulos et al.	604	890.1	
	AI	5	7	6	7	1	2	5	6/98	Crain et al.	514	282	
	AJ	5	6	3	3	2	5	9	5/97	Qin et al.	514	282	
	AK	5	6	2	4	9	3	2	4/97	Qin et al.	514	282	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AL	19	6	5	1	5	5	1	6/98	DE	A61K	31/485		
	AM	29	7	1	9	7	0	4	2/97	DE	A61K	31/485		
	AN	4	3	2	5	4	6	5	2/95	DE	A61K	31/485	X	
	AO	2	2	2	2	0	3	9	11/72	DE	A61K	27/00		
	AP	0	9	1	3	1	5	2	6/99	EP	A61K	31/485		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AQ	Abstract, Cancer Chemother Pharmacol (1998); 42(4):287-91.
	AR	Yuan et al., Drug and Alcohol Dependence (1998); 52:161-165.
	AS	Gan et al., "Opioid-Sparing Effects of a Low-Dose Infusion of Naloxone in Patient-Administered Morphine Sulfate," Anesthesiology (1997), 87(5):1075-1080.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE								ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081		
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)										APPLICANT(S): Curtis Wright et al.				
										FILING DATE: February 8, 2001		GROUP: 1615		
U.S. PATENT DOCUMENTS														
*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	BA	5	6	1	6	6	0	1	4/97	Khanna et al.	514	399		
	BB	5	5	8	5	3	4	8	12/96	Crain et al.	514	12		
	BC	5	5	8	0	8	7	6	12/96	Crain et al.	514	282		
	BD	5	5	7	8	7	2	5	11/96	Portoghese et al.	546	35		
	BE	5	5	7	4	0	5	2	11/96	Rose et al.	514	343		
	BF	5	5	5	6	8	3	8	9/96	Mayer et al.	514	25		
	BG	5	5	3	4	4	9	2	7/96	Aston et al.	514	608		
	BH	5	5	1	4	6	8	0	5/96	Weber et al.	514	249		
	BI	5	5	1	2	5	7	8	4/96	Crain et al.	514	282		
	BJ	5	5	0	2	0	5	8	3/96	Mayer et al.	514	289		
	BK	5	4	8	6	3	6	2	1/96	Kitchell et al.	424	426		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BL	0	6	4	7	4	4	8	4/95	EP	A61K	31/485		
	BM	0	3	5	2	3	6	1	1/90	EP	A61K	31/485		
	BN	0	2	0	5	2	8	2	12/86	EP	A61K	9/22		
	BO	9	9	3	2	1	2	0	7/99	WO	A61K	31/485		
	BP	9	8	3	5	6	7	9	8/98	WO	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	BQ	Shen et al., "Ultra-Low Doses of Naltrexone or Etorphine Increase Morphine's Antinociceptive Potency and Attenuate Tolerance/Dependence in Mice," Brain Research (1997), 757:176-190.												
	BR	Yuan et al., Clinical Trials and Therapeutics (1997), 61:467-475.												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:
200.1133SERIAL NO.:
09/781,081

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S):
Curtis Wright et al.FILING DATE:
February 8, 2001GROUP:
1615

U.S. PATENT DOCUMENTS

*EXAMINER R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA	5	4	7	2	9	4	3	12/95	Crain et al.	514	12	
	CB	5	4	5	7	2	0	8	10/95	Portoghese et al.	546	35	
	CC	5	4	2	6	1	1	2	6/95	Zagon et al.	514	282	
	CD	5	3	7	6	6	6	2	12/94	Ockert	514	282	
	CE	5	3	5	6	9	0	0	10/94	Bihari et al.	514	282	
	CF	5	3	5	2	6	8	3	10/94	Mayer et al.	514	289	
	CG	5	3	5	2	6	8	0	10/94	Portoghese et al.	514	279	
	CH	5	3	2	1	0	1	2	6/94	Mayer et al.	514	25	
	CI	5	3	1	7	0	2	2	5/94	Borsodi et al.	514	282	
	CJ	5	3	1	6	7	5	9	5/94	Rose et al.	424	10	
	CK	5	2	7	3	7	6	0	12/93	Oshlack et al.	424	486	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	CL	9	7	3	3	5	6	6	9/97	WO	A61K	9/20		
	CM	9	6	0	2	2	5	1	2/96	WO	A61K	31/485		
	CN	9	5	0	3	8	0	4	2/95	WO	A61K	31/485		
	CO	9	4	0	6	4	2	6	3/94	WO	A61K	31/46		
	CP	8	3	0	3	1	9	7	9/83	WO	A61K	9/22		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CQ	Mendelson J., et al, "Buprenorphine and Naloxone Interactions in Opiate-Dependent Volunteers," Clin. Phar. Ther. (1996), 60:105-114.
	CR	Walsh et al., "Effects of Naltrexone on Response to Intravenous Cocain, Hydromorphone and their Combination in Humans," (1996).

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Curtis Wright et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	DA	5	2	5	6	6	6	9	10/93	Askanazi et al.	514	282		
	DB	5	2	3	6	7	1	4	8/93	Lee et al.	424	449		
	DC	5	2	2	5	4	4	0	7/93	London et al.	514	535		
	DD	5	1	4	9	5	3	8	9/92	Granger et al.	424	449		
	DE	5	1	0	2	8	8	7	4/92	Goldberg	514	282		
	DF	5	0	9	6	7	1	5	3/92	Sinclair	424	449		
	DG	5	0	8	6	0	5	8	2/92	Sinclair et al.	514	282		
	DH	5	0	7	5	3	4	1	12/91	Mendelson et al.	514	282		
	DI	4	9	3	5	4	2	8	6/90	Lewis	514	282		
	DJ	4	8	8	9	8	6	0	12/89	Rzeszotarski et al.	514	282		
	DK	4	8	8	2	3	3	5	11/89	Sinclair	514	282		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	DL													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	DM	Chih-Cheng Chien, Neuroscience Letters 190 (1995), 137-139.												
	DN	Crain et al., "Ultra-Low Concentrations of Naloxone Selectively Antagonize Excitatory Effects of Morphine on Sensory Neurons, Thereby Increasing Its Antinociceptive Potency and Attenuating Tolerance/Dependence During Chronic Cotreatment," Proc. Natl. Acad. Sci. USA (1995), 92:10540-10544.												
	DO	Hanson, Analgesic, Antipyretic and Anti-Inflammatory Drugs in Remington's Science and Practice of Pharmacy (1995), 2:1207.												
	DP	Physician's Desk Reference 48 th Ed. (1994) Montvale, NJ, 2120-2121.												
	DQ	Foss et al., J. Clin Pharmacol (1993), 33:747-751.												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Curtis Wright et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	EA	4	8	7	3	0	7	6	10/89	Fishman et al.	412	10		
	EB	4	8	6	1	7	8	1	8/89	Goldberg	514	282		
	EC	4	8	6	1	5	9	8	8/89	Oshlack et al.				
	ED	4	8	0	6	5	5	8	2/89	Wuest et al.	514	381		
	EE	4	8	0	6	5	4	3	2/89	Choi	514	464		
	EF	4	8	0	6	3	4	1	2/89	Chien et al.	424	448		
	EG	4	8	0	3	2	0	8	2/89	Pasternak	514	282		
	EH	4	7	8	5	0	0	0	11/88	Kreek et al.	514	282		
	EI	4	7	6	9	3	7	2	9/88	Kreek et al.	514	282		
	EJ	4	7	6	0	0	6	9	7/88	Rzeszotarski et al.	514	282		
	EK	4	7	3	0	0	4	8	3/88	Portoghese et al.	546	45		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	EL													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	EM	Holmes et al., Anesth. Analg. (1993), 77:1166-73.												
	EN	Miaskowski et al., Brain Research (1992), 596:41-45.												
	EO	Weinhold et al., "Buprenorphine Alone and In Combination with Naltrexone in Non-Dependent Humans," Drug and Alcohol Dependence (1992), 30:263-274.												
	EP	Cappel et al., Pharma. Bioch. & Behav. (1989), 34:425-427.												
	EQ	Vaccarino et al., Pain (1989), 36:103-109.												
	ER	Gonzalez et al., "Naltrexone: A Review of its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Efficacy in the Management of Opioid Dependence," Drugs (1988), 35:192-213.												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Curtis Wright et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINE R INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	FA	4	7	1	9	2	1	5	1/88	Goldberg	514	282		
	FB	4	6	6	1	4	9	2	4/87	Lewis et al.	514	282		
	FC	4	6	0	8	3	7	6	8/86	Pasternak	514	282		
	FD	4	5	8	2	8	3	5	4/86	Lewis et al.	514	282		
	FE	4	5	7	3	9	9	5	3/86	Chen et al.	604	896		
	FF	4	4	6	4	3	7	8	8/84	Hussain et al.	424	260		
	FG	4	4	5	7	9	3	3	7/84	Gordon et al.	424	260		
	FH	4	4	5	1	4	7	0	5/84	Ganti	424	260		
	FI	4	4	0	1	6	7	2	8/83	Portoghese et al.	424	260		
	FJ	4	1	7	6	1	8	6	11/79	Goldberg	424	260		
	FK	3	9	6	6	9	4	0	6/76	Pachter et al.	424	260		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	FL													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	FM	Sunshine, et al., "Analgesic Efficacy of Pentazocine Versus a Pentazocine-Naloxone Combination Following Oral Administration," Clin. J. Pain (1988), 4:35-40.												
	FN	Wang et al., "Crossover and Parallel Study of Oral Analgesics," J. clin. Pharmacol (1981), 21:162-168.												
	FO													
	FP													
	FQ													
	FR													
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): Curtis Wright et al.								
						FILING DATE: February 8, 2001		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINE R INITIAL		DOCUMENT-NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	GA	3	8	7	9	5	5	5	4/75	Pachter et al.	424	260		
	GB	3	7	7	3	9	5	5	11/73	Pachter et al.	424	260		
	GC	3	6	7	6	5	5	7	7/72	Lachman et al.	424	260		
	GD	3	4	9	3	6	5	7	2/70	Lewenstein et al.	424	260		
	GE	3	3	3	2	9	5	0	7/67	Blumberg et al.	260	285		
	GF	2	7	7	0	5	6	9	11/56	Fromherz et al.	167	65		
	GG													
	GH													
	GI													
	GJ													
	GK													
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	GL													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	GM													
	GN													
	GO													
	GP													
	GQ													
	GR													
	GS													
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Curtis WRIGHT, et al.

FILING DATE: February 8,
2001

GROUP: 1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6	2	2	8	8	6	3	05/08/01	Palermo et al.	514	282	
	AB	6	2	7	7	3	8	4	08/21/01	Kaiko et al.	424	400	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AC	WO	98	2	5	6	1	3	06/18/98	EPO	A61K	31/485	Abstract	
	AD	WO	00	3	8	6	4	9	07/06/00	EPO	A61K	9/00	Abstract	

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AE	Press Release entitled "International Patent Application To Be Published on Abuse-Resistant Pain Reliever Being Developed by Purdue Pharma" August 8, 2001.											
	AF	Paronis, et al., Increased Analgesic Potency of Mu Agonists after Continuous Naloxone Infusion in Rats, J Pharm. Exper. Ther. 1991 259(2) pg 582-589											
	AG	Yoburn, et al., Supersensitivity to Opioid Analgesics Following Chronic Opioid Antagonist Treatment: Relationship to Receptor Selectivity, Pharmacol. Bio. Beh. 1995 51 (2) pg 535-539											
	AH	Crain, et al., Acute thermal hyperalgesia elicited by low-dose morphine in normal mice is blocked by ultra-low-dose naltrexone, unmasking potent opioid analgesia, Brain Res. 2001 888 pg 75-82											
	AI	Zhang, et al., Down-Regulation of μ -Opioid Receptors in Rat and Monkey Dorsal Root Ganglion Neurons and Spinal Cord After Peripheral Axotomy, Neuroscience 1998 82, pg 223-240											
	AJ	Abdulla, et al., Axotomy reduces the effect of analgesic opioids yet increases the effect of nociceptin on dorsal root ganglion neurons, J. Neuro Sci 1998 18, pg 9685-9694											
	AK	Di Giannuario, et al., Orphanin FQ reduces morphine-induced dopamine release in the nucleus accumbens: a microdialysis study in rats, Neurosci. Lett. 1999 272, pg 183-186											
	AL	Ciccocioppo, et al., Effect of nociceptin/orphanin FQ on the rewarding properties of morphine, Eur. J. Pharmacol. 2000 404, pg 153-159											
	AM												
	AN												

EXAMINER

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1133		SERIAL NO.: 09/781,081	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): Curtis WRIGHT, et al.			
				FILING DATE: February 8, 2001		GROUP: 1615	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AA	Benfey, Function of Myocardial α -ADRENOCEPTORS: Life Sciences (1982) Vol. 31 pg 101-112					
	AB	Levine, et al., Potentiation of Pentazocine Analgesia by Low-dose Naloxone: J. Clin. Invest. (1988) Vol. 82 pg. 1574-1577					
	AC	Yoburn, et al., Opioid Antagonist-induced Receptor Upregulation: Effects of Concurrent Agonist Administration, (1994) (Publication Date): Brain Research Bulletin, Vol. 33 pg 237-240					
	AD	Bunzow, et al., Molecular cloning and tissue distribution of a putative member of the rat opioid receptor gene family that is not-a μ , δ or κ opioid receptor type: FEBS Letters 347 (1994) pg. 284-288					
	AE	Mollereau, et al., ORL1, a novel member of the opioid receptor family: Cloning, functional expression and localization: FEBS Letters 341 (1994) pg. 33-38					
	AF	Wang, et al., cDNA cloning of an orphan opiate receptor gene family member and its splice variant: FEBS Letters 348 (1994) 75-79					
	AG	Suzuki, et al., Morphine conditioned place preference after chronic treatment with naloxone in the rat: Research Communications in Substances of Abuse. (1991) Vol. 12, No. 3 pg. 119-131					
EXAMINER				DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							